



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :  
Francis J. GILES et al. : Examiner: Cybille Delacroix-Muirheid  
Serial No.: 10/729,387 : Group Art Unit: 1614  
Filed: December 8, 2003 :

For: PHARMACEUTICAL COMBINATIONS AND METHODS FOR THE  
TREATMENT OF LEUKEMIA

**DECLARATION BY FRANCIS J. GILES UNDER 37 CFR §1.132**  
**REGARDING PUBLICATIONS BY NON-INVENTOR AUTHORS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SIR:

I, Francis J. Giles, being duly warned, declare that:

I and Srdan Verstovsek are the co-inventors of the claimed invention in the above-captioned application (see the attached list of claims).

I have been an employee of University of Texas, M. D. Anderson Cancer Center  
since 1997.

By virtue of an agreement between between University of Texas, M. D. Anderson Cancer Center and Shire Biochem Inc., the instant application is assigned to Shire Biochem Inc.

By virtue of an agreement between The University of Texas, M. D. Anderson Cancer Center and Shire Biochem Inc., Shire Biochem retained the services of The University of Texas, M. D. Anderson Cancer Center to perform, in the ordinary course of business, preclinical laboratory study entitled "Preclinical evaluation of Troxacitabine and STI571 combination treatments of Philadelphia chromosome-positive STI571-resistant leukemia." The study was performed for Shire Biochem, and particularly under the direction, supervision and control of myself and Srdan Verstovsek. The results of this study are presented in the following coauthored by myself, Srdan Verstovsek, and also Nada Orsolic, Miloslav Beran, Jorge Cortes, Maher Albitar, and Hagop Kantarjian:

"Troxytyl and STI571 Combination Therapy for Chronic Myeloid Leukemia: Preclinical In Vitro and In Vivo Evaluation", Blood, vol. 100, no. 11, (2002), Abstract No. 3107.

To the extent the claimed invention is disclosed in the above listed of publication, such disclosure is of mine and Srdan Verstovsek's invention. The other coauthors listed on the publication, namely Nada Orsolic, Miloslav Beran, Jorge Cortes, Maher Albitar, and

Hagop Kantarjian, are not inventors, and contributed to aspects which were not part of the conception of the subject matter of the claims of this application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

  
\_\_\_\_\_  
Francis J. Giles

Date: 10/28/05